REMARKS

Support for the Amendments

In the amendment, claims 18, 20, 22-23, 25 and 27 have been amended, and claims 19, 21, 24 and 26 have been canceled without prejudice as to patentability. Such amendments are fully supported in the specification as originally filed. No new matter has been added.

More particularly, claim 18 is amended to read altering the nerve "non-surgically". Similarly, claim 23 is amended to read that the nerve has been altered "non-surgically". Support for such amendments can be found throughout the specification, particularly on page 3, paragraph [0019], which states, "non-surgical is defined as a method that does not rely on an open surgical incision of the skin or any other tissue for open, visualized placement of a biocompatible substance".

Claim 18 is further amended to read "placing a gel substance into the fascial tunnel through which the tibial nerve or the branch of the tibial nerve passes". Similarly, claim 23 is further amended to read "by placing a gel substance into the fascial tunnel through which the tibial nerve or the branch of the tibial nerve passes". Support for the amendment of "placing" or "placement" can be found throughout the specification (see paragraph [0011], [0016], [0018], [0019], [0022], [0024]-[0027], [0029], [0035], [0036], [0038] and [0040]), wherein phrases like "placement of the gel" or "placement of a biocompatible substance" or sentences like "a biocompatible substance is placed" are frequently used. As to the amendment of "fascial tunnel through which the tibial nerve or the branch of the tibial nerve passes", support can be found on page 4, paragraph [0025], wherein it is described that a needle tip "was gently slipped beneath the fascial edge of the soleus muscle by the tibial nerve and artery into the deep posterior fascial compartment of the posterior tibial neurovascular tunnel, which is the neurovascular tunnel for the posterior tibial nerve and its proximal branches" and that "When the tip of the needle was at the mid soleus muscle belly, the collagen mixture was slowly injected into the posterior tibial tunnel". It is well known in the art that all nerves pass through fascial tunnels. Accordingly, the amendment of "placing a gel substance into the fascial tunnel through which the tibial nerve or the branch of the tibial nerve passes" in claims 18 and 23 is adequately supported by the specification as originally filed.

Claims 18 and 23 are amended to refer to the tibial nerve and a branch of the tibial nerve. Such language is fully supported by the specification (see page 4, paragraph [0025]).

Reasons Why the Amendments Are Necessary and Were Not Earlier Presented

Applicant has amended independent claim 18 to incorporate subject matters of dependent claims 19 and 21 as well as to clarify the metes and bounds of what is encompassed by the claim. Similarly, independent claim 23 has been amended to incorporate subject matters of claims 24 and 26 as well as to clarify the metes and bounds of what is encompassed by the claim. Such amendments to claims 18 and 23 are presented to address the 35 U.S.C. §112, first and second paragraph, rejections, some of which were newly raised by the Examiner in the Final Office Action.

Claims 18 and 23 have further been amended to recite "non-surgically". Such amendment is presented to address the 35 U.S.C. §102 and §103 rejections that were newly raised by the Examiner in the Final Office Action.

Claims 19, 21, 24 and 26 have been canceled. Claims 20, 22, 25 and 27 have been amended to correct the dependency and to better define the terminology that is unclear to the Examiner. Such amendment is presented to address 35 U.S.C. §112, second paragraph, rejection, some of which were newly raised by the Examiner in the Final Office Action.

Applicant believes that the above amendments are necessary to put the claims in condition for allowance. Such amendments were not earlier presented since some of the amendments are presented in direct response to the new ground(s) of rejection raised in the Final Office Action. Applicant also draws the Examiner's attention that the claims originally filed and subsequently elected were replaced with a new set of claims in the last response to the previous Office Action. The new claims that were submitted previously were meant to better define the present invention.

In view of the above remarks, Applicant respectfully requests that the amendments presented above be entered.

35 U.S.C. § 112, First Paragraph, Rejection

Claims 18-27 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

As discussed above, claims 18, 20, 22-23, 25 and 27 have been amended, and claims 19, 21, 24 and 26 have been canceled without prejudice as to patentability. Applicant believes that the amended claims 18-27 fully comply with the written description requirement and are fully enabled by the specification as originally filed.

The Examiner states that the specification fails to provide literal support for the term "non-transgenic" or "non-transgenically". Applicant has amended claims 18 and 23 by deleting the term "non-transgenically" and "non-transgenic", respectively.

Claims 18 is further amended by incorporating the subject matters of claims 19 and 21 to recite that a gel substance is placed into the fascial tunnel through which a tibial nerve or a branch of a tibial nerve passes. Similarly, claim 23 is further amended to incorporate the subject matters of claims 24 and 26 to recite that a gel substance is placed into the fascial tunnel through which a tibial nerve or a branch of a tibial nerve passes.

The Examiner maintains the rejection over claims 18-27 for failing to provide enablement for any other model encompassed by the claims. Applicant has amended claims 18 and 23 to refer to the tibial nerve and a branch of the tibial nerve. As discussed above, such amendment is well supported and the scope of the amended claims is well enabled by the specification.

With respect to the Lundborg reference (Journal of Hand Surgery, Vol. 7, pages 252-259, 1982) cited by the Examiner, Applicant submits that Lundborg discloses compressing median nerve on human hands (see page 252, under "Material and methods"). That is, Lundborg uses human models rather than non-human mammalian models. Thus, Lundborg is improper.

In view of the above remarks, Applicant believes that claims 18-27 as amended are fully enabled. Accordingly, the rejection of claims 18-27 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

35 U.S.C. § 112, Second Paragraph, Rejection

Claims 18-27 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is respectfully traversed.

The Examiner states that the term "non-traumatic" is not clear as to whether it is applicable to the animal or to the nerve. Applicant clarifies that "non-traumatic" is meant to apply to the nerve particularly, although the method as claimed is also non-traumatic to the animal. This notion is supported by the specification, which states, "non-traumatic is defined as a method that does not cause acute pain, an immune reaction, inflammation, or is not due to direct trauma to the nerves by methods that would include but not be limited to direct irritation, cutting, crushing, or binding" (emphasis added, see page 2, paragraph [0015]). Claims 18 and 23 as amended recite "altering a tibial nerve or a branch of a tibial nerve of a mammal ... non-traumatically" and "a tibial nerve or a branch of a tibial nerve in the mammal has been altered ... no traumatically", respectively.

The Examiner also states that the phrase "physiologic change" in claims 18 and 23 is unclear. Applicant addresses this rejection by deleting the phrase from the claims and further amending dependent claims 22 and 27 to recite "the placement of the gel substance leads to the development of allodynia, hyperalgesia or both".

The Examiner further states that claims 23-27 are unclear because the metes and bounds of what is encompassed by the phrase "around the nerve" are unclear. Applicant has amended the claims to recite "into the fascial tunnel through which the tibial nerve or the branch of the tibial nerve passes" to clarify where the gel substance is being placed relative to the nerve. As discussed above, such amendment is adequately supported by the specification.

In view of the above remarks, Applicant believes that claims 18-27 as amended are definite. Accordingly the rejection of claims 18-27 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

35 U.S.C. § 102 Rejection

Claims 18 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Reyna (ICLAS, Palma de Malloren, May 26-28, page 226, 1999). This rejection is respectfully traversed.

Reyna reference discloses a biogenic and non-traumatic animal model of chronic pain. The methodology used in Reyna includes exposing the posterior tibial nerve on one leg of the animal (emphasis added, see under "Methods"), which indicates an open surgical procedure.

Reyna does not teach a non-surgical method of generating a neurogenic pain model. In direct contrast, the present invention teaches a method of producing an animal model for persistent neurogenic pain by altering a tibial nerve or a branch of a tibial nerve non-surgically (emphasis added) as described in claim 18 as amended. The present invention further teaches an animal pain model, wherein a tibial nerve or a branch of a tibial nerve has been altered non-surgically (emphasis added) as described in claim 23 as amended. The term "non-surgical" is being defined as "a method that does not rely on an open surgical incision of the skin or any other tissue for open, visualized placement of a biocompatible substance" in the context of the present invention (see page 3, paragraph [0019]). That is, the placement of the gel substance is not visualized. In fact, as described in the present invention, one would first identify the external anatomic landmarks of the posterior popliteal, followed by mentally visualizing (emphasis added) with kinesthetic techniques the internal anatomy of the area including the posterior tibial nerve with its artery. Kinesthetic techniques are techniques that use the kinesthetic sense or the sense by which movement, weight and position are commonly perceived (see page 4, paragraph [0025]). That is, the tibial nerve is not exposed for visualization during the placement of the gel substance in the present invention.

Additionally Reyna does not disclose a gel substance or a collagen as the biocompatible substance to be introduced near the nerve. In contrast, the present invention as claimed teaches the placement of a gel substance, preferably, a collagen, into the fascial tunnel through which a tibial nerve or a branch of a tibial nerve passes.

In view of the above remarks, Applicant believes that Reyna does not teach each and every element of the present invention as claimed. In fact, Reyna teaches away from the present invention as claimed. Thus, the rejection of claims 18 and 23 35 U.S.C. § 102(b) should be withdrawn.

35 U.S.C. § 103 Rejection

Claims 19-27 stand rejected under 35 U.S.C. § 103 as being unpatentable over Reyna in view of Ford (Laryngoscope, Vol. 96, pages 1248-1257, 1986). This rejection is respectfully traversed.

As discussed above, Reyna discloses an open surgical method for generating a pain model, which is in direct contrast to the present invention claiming a non-surgical method for generating a pain model. Additionally, Reyna does not disclose a gel substance or a collagen.

Ford discloses injection of bovine collage into canine vocal folds to correct glottic insufficiency. Ford does not disclose a non-surgical method of generating an animal pain model.

The Examiner states that one of ordinary skill in the art would have been sufficiently motivated to combine the teachings of Reyna and Ford to reproduce the present invention. Applicant respectfully disagrees.

It is well known in the art that biocompatible substances such as collagen are meant to minimize any immune response to prevent the development of any painful tissue conditions instead of causing pain. In fact, many biocompatible substances are placed near nerves in many medical and surgical procedures without development of neurogenic pain. Thus, it would be against common knowledge in the art for a skilled artisan to use collagen for producing a pain model at the time the present invention was made.

Furthermore, there is no suggestion or mentioning from Reyna and Ford, alone or combined, that collagen can be used to generate a persistent neurogenic pain model. Even though one skilled artisan were motivated to combine the teachings of Reyna and Ford, he or she would still not be able to produce the present invention due to the fact that Reyna, the primary reference, teaches away from the present invention.

In view of the above remarks, Applicant believes that Reyna in view of Ford does not render the present invention obvious. Accordingly, the rejection of claims 19-27 under 35 U.S.C. § 103 should be withdrawn.

CONCLUSION

In view of the foregoing amendment and remarks, it is respectfully submitted that this application is in condition for allowance.

The Examiner is invited to contact the undersigned agent at (713) 787-1512 with any comments or suggestions relating to the referenced patent application.

This paper is accompanied by a request for a two-month extension of time and authorization to charge Howrey Simon Arnold & White Deposit Account No. 01-2508/13629.0002.NPUS00 for the appropriate fees. Should any additional fee be required for any reason in connection with this paper, the Commissioner is authorized to deduct said fees from the same deposit account.

Respectfully submitted,

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